REMARKS

An Office Action was mailed in the above-captioned application on May 13, 2008. Claims 1-10 were pending in the application. Claims 1-10 were rejected. This Amendment and Remarks document is submitted in response to said Office Action.

Sequence Rules Compliance

The Office action and attached Notice to Comply indicate that the application contains sequence disclosures but the application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 because there is no statement that the paper copy of the sequence listing and the CRF are the same. Enclosed herewith is the statement. With the submission of this statement, Applicant believes that all the requirements of 37 C.F.R. §§ 1.821-1.825 have been met.

The Rejection under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 1-10 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art the inventors, at the time the application was filed, had possession of the claimed invention.

The first paragraph of Section 112 requires that a patent application be written so as to "enable any person skilled in the art to which it pertains . . . to make and use the same." A specification is presumed to be enabling absent "a reason to doubt the objective truth of the statements contained therein." *In re Marzocchi*, 169 USPQ 367, 369 (C.C.P.A 1971). Further, a specification "may be enabling even though some experimentation is necessary," *United States v. Teletronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), so long as the amount of experimentation required is not "undue experimentation." *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The test is whether the specification "provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Further, it is a tenet of patent law that an applicant need not teach what the skilled artisan already knows. Instead, it is preferred that an applicant "omit what is known in the art." *Hybritech Inc. v.*

Monoclonal Antibodies, 231 USPQ 81, 94 (Fed. Cir. 1986). With this standard in mind, the rejection is discussed below.

Regarding claims 1-7, the Office action states that these claims are broadly drawn to a method of assessing susceptibility of an individual to treatment of an inflammatory disease with fish oil, comprising determining the genotype of the individual in relation to polymorphisms at the TNF-α -308, LT-α +252 and/or IL-6 -174 alleles; and inferring therefrom whether said individual responds well to treatment with fish oil. Regarding claims 8-10, the Office action states that the claims are drawn to a method for the treatment of an inflammatory disease in a patient, which comprises assessing the susceptibility of an individual to treatment of an inflammatory disease with fish oil, said assessment comprising: a) determining the genotype of the individual in relation to polymorphisms at the TNF-α-308, LT-α +252 and/or IL-6 -174 alleles; and b) inferring therefrom whether said individual responds well to treatment with fish oil; and treating said individual with an appropriate amount of fish oil. The rejection states that, for various reasons, it is the position of the Examiner that undue experimentation would be required for one of skill in the art to perform the method of the claim as broadly written.

Without acquiescing in the rejection, and solely in the interest of expediting prosecution, Claims 1-10 have been cancelled, and new claims 11-19 have been presented in order to clarify the claimed invention. Applicants reserve the right to pursue cancelled subject matter in a continuing application.

The pending claims no longer refer to treatment of an inflammatory disorder. Claims 11-14 are now directed to methods of assessing the sensitivity of an individual to the anti-inflammatory effects of fish oil comprising determining the genotype of the IL-6 -174 allele, determining the genotype of the LT-α +252 allele, and determining the inherent TNF-α production of the individual in various combinations. Support for these claims can be found throughout the specification, for example, see page 35, line 28, to page 36, line 10.

Claims 15-19 are now directed to a method of reducing TNF-α production in an individual, comprising determining the genotype of at least one of the LT-α +252 allele and the IL-6 -174 allele; and administering to said individual a therapeutically effective amount of fish oil based on the genotype of the individual. Support for these claims can be found throughout the specification, for example, see page 33, line 1, to page 34, line 9.

Applicants believe the pending claims address the Examiner's concerns concerning the recitation of a treatment of an inflammatory disease, since this phrase is no longer included in the claims. TNF-α reduction is a known anti-inflammatory action of fish oil, but fish oil not always effective in all individuals (page 2, lines 18-23). As explained in the specification, the present inventors have recognized that the sensitivity of an individual to the inflammation suppressing effects of fish oil on TNF-α production is linked to genetic variation encoded by, or associated with, the TNF-α -308, LT-α +252 and IL-6 -174 single nucleotide polymorphisms (SNP's). The inflammation suppressing effects of fish oil on TNF-α production have also been shown to be related to the inherent level of production of TNF-α by cells. Thus, the present invention allows the targeting of fish oil to those patients most likely to benefit from it. (page 4, lines 27-28).

In view of the foregoing arguments and amendments, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph is respectfully requested.

The Rejection under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claims 1-10 under 35 U.S.C. § 112, second paragraph. The second paragraph of Section 112 requires that the claims set out and circumscribe a particular area which applicants regard as their invention with a *reasonable* degree of precision and particularity.

Specifically, the rejection states that Claims 1, 7 and 8 contain the indefinite recitations of "polymorphisms at the TNF-α -308, LT-α +252 and/or IL-6 -174 alleles." Claims 1, 7 and 8 have been cancelled. The objected-to phrase does not appear in the new claims. Rather the new claims refer to specific polymorphisms or specific combinations of polymorphisms and are believed to be clear.

Reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph is respectfully requested.

Closing Remarks

Applicant believes that the pending claims are in condition for allowance. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-1970, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-1970.

Respectfully submitted,

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